REMARKS

Claims 21-63 are currently pending in the present application.

Substance of Personal Interview

Applicant's representative, Kevin Dunleavy, and the inventor Dr. Charles Boucher conducted a personal interview with Examiner Mahatan and Supervisory Examiner Woodward on November 1, 2004. At the interview, the sole outstanding rejection of the claims under 35 U.S.C. §112 was discussed, and there was a brief discussion of the features of the claims that distinguish the invention over "CTSHIV: A Knowledge-Based System for the Management of HIV-infected Patients," Pazzani et al., *Proceedings: Intelligent Information Systems, IIS' 97* (CAT. No. 97TB100201), 1997, pages 7-13 (hereinafter "Pazzani et al."). Independent claims 21, 44, 51 and 60 were discussed. The substance of the discussion of the sole outstanding rejection is reflected in the comments provided below.

At the interview, the applicant presented additional evidence, in the form of the following two papers, for the purpose of demonstrating how a skilled person would be able to carry out the invention using the clinical data contained in these papers:

(1) "Genotypic and phenotypic analyses of HIV-1 in antretroviral-experienced patients treated with tenofovir DF," Margot, N.A., et al., *AIDS*, 2002, **16**:1227-1235; and

(2) "Clinically relevant interpretation of genotype for resistance to abacavir," Brun-Vézinet, F. et al., *AIDS*, 2003, **17**:1795-1802.

On the basis of these publications, Dr. Boucher described how a skilled person would go about carrying out the invention as claimed.

At the interview, the Examiner's indicated that if applicant were to formally submit these documents addressing the 35 U.S.C. §112 rejection, they would not be dismissed out of hand, despite the fact that the present application is under final rejection. Accordingly, applicant encloses herewith copies of these documents for formal submission in the above-identified application.

Rejection Under 35 U.S.C. § 112

The Examiner rejected claims 21-63 under 35 U.S.C. §112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method for effecting computer implemented decision-support in selection of a drug therapy, whereby a rules database is used. The rules database used by the method of the present invention comprises a number of associated rules for each available drug used in treatment of a viral disease, with each rule used to give an indication the suitability of the drug for treatment of a specific viral genotype.

The present invention is a significant improvement over the Pazzani et al. system since the present invention allows the inclusion of significant additional data, including clinical data and in vivo testing, that were not included in the Pazzani et al. system, which was limited to the use of in vitro data. This expands the universe of available data upon which treatment decisions can be based, thereby offering a significant improvement in the decision-making process. Also, the present invention provides a ranking of the drugs, relative to one another, to provide an enhanced level of objectivity to the information contained in the system. As claimed in claim 21, the present invention not only includes this additional data, and provides such a ranking, but also weight the data based on a confidence value objectively related to the type of test data (e.g. clinical, in vivo, or in vitro) to thereby provide a more reliable usage of the data in the decision-making process. As claimed in claim 44, a ranking of the suitability of different combinations of drugs is provided. As claimed in claim 51, a ranking of the suitability is provided based on the resistance level of the genotype for the drug when present at a certain drug level in a patient. As claimed in claim 60, a ranking of the suitability is provided and wherein the clade of the virus is employed in the decision-making process.

The Examiner raises several objections, all of which relate to the fact that the present specification does not give a detailed description of exactly how to derive each rule in the rules database. However, the applicant submits that it is not necessary for the specification to provide this level of detail because a person of ordinary skill in the art is already capable of deriving the rules to be used for the rules database and thus does not need to be taught how to do this by the present specification. See e.g. MPEP Section 2164.05(b). Moreover, the nature of the invention is such that minor differences in the derivation of such rules are of little consequence since drugs are ranked relative to one another by the method of the invention.

For example, the rules database of the present invention may be merely a codification of the decision-making process that is already used every day by clinicians throughout the world to

determine the proper drug therapy. More specifically, clinicians are required to make decisions every day about the proper drug therapy to give patients. That the clinicians are capable of making such decisions is evidenced by the fact that clinicians prescribe drug therapy for patients every day. There is no need for these clinicians to consult the present patent specification to perform this task. Instead, these clinicians employ at least their experience, common general knowledge, diagnosis, and knowledge of the medical literature to make these decisions. Also, the clinicians apply certain rules in the decision-making process to determine the weight to give to each piece of information in the final decision. Although the rules are applied in the brain of the clinician, the clinician is capable of elucidating these rules and thereby creating the database for use in the present invention.

Thus, as the specification states, the actual rule derivation process will be performed by members of a core committee who will exercise their judgment based on the information presented to them, in much the same way that clinicians formulate drug therapies for their patients on a daily basis. Therefore, since the provision of a rules database can be carried out by skilled persons using their common general knowledge, and, in actual fact, is carried out by clinicians every day, there is no need for the specification of the present application to disclose, in detail, a specific algorithm/step/procedure for creating a specific rules database. The claims cover any method for assigning these values that involves use of the information specified in the claims, and a skilled person, exercising common general knowledge, is capable of assigning these values without requiring further guidance from the present application.

Given the mass of literature currently available on, for example, HIV drug resistance, the average clinician/researcher simply cannot assimilate all the data available within a reasonable time frame and still manage his or her practice and/or research. The current invention allows the user to enter HIV or viral strain data, for example, and take advantage of the work of the core committee who has reviewed the relevant literature on the subject. In this manner, every clinician can formulate drug therapies in an objective manner, with access to all of the relevant information currently available on the subject. As a result, the clinician can make timely and reasonable recommendations using the method of the present invention that presumably will be better than the recommendations that are currently being made, due to having access to all relevant information and the reduced possibility for error in the application of the decision-making rules due to its implementation by a computer.

The clinician/researcher can be assured that the computer implemented decision-support not only is current and precise but also peer-reviewed and tested. Also, due to the fact that the

methods of the present invention rank drug therapies relative to one another, an objective system for making decisions is generated since the results of the method, i.e. the ranking of the therapies, are rendered independent of the specific rules used by the core committee since the same rules are applied to each drug therapy and the drug therapies are ranked relative to one another. The use of this ranking system adds a further level of reliability and objectivity to the system of the present invention that is not found in some other expert systems.

Applicant respectfully submits that all the claims are in condition for allowance and requests that the §112, first paragraph rejection be withdrawn.

Respectfully Submitted,

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Enclosures:

(1) "Genotypic and phenotypic analyses of HIV-1 in antretroviral-experienced patients treated with tenofovir DF," Margot, N.A., et al., *AIDS*, 2002, **16**:1227-1235; and

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